



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/533,219 03/23/00 KUKKOLA

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001095
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HM22/0326

EXAMINER

TRUONG, T

ART UNIT

PAPER NUMBER

1624

DATE MAILED:

10
03/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/533,219

Applicant(s)

KUKKOLA, PAIVI JANNA

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 11, 12, 14, and 16-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 11, 12, 14, and 16-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,3,6,8.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Applicant's preliminary amendment has been entered. Accordingly, claims 1-8, 10, 13, and 15 are cancelled, leaving claims 9, 11, 12, 14, and 16-22 for consideration.

Double Patenting

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 9, 11, 12, 14, 16-22 are provisionally rejected under the judicially created doctrine of **obviousness-type** double patenting as being unpatentable over claims 9, 11, 12, 14, and 16-20 of copending Application No. 09/702,634. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same compounds, compositions and methods are claimed in both instances, they only differ in their dependency.
2. Claims 9, 11, 12, 14, and 16-22 are provisionally rejected under the judicially created doctrine of **non-obviousness type** double patenting over claims 1-8, 10, 13, and 15 of copending

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Application No. 09/702,634. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the compounds, compositions, and methods claimed herein are embraced by the genus, compositions and methods claimed in co-pending application 09/702,634.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

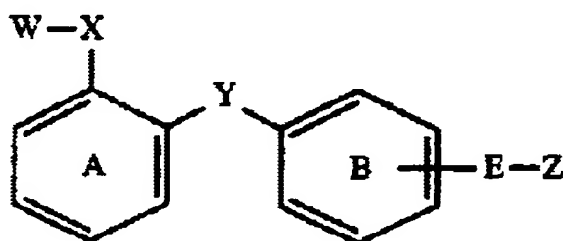
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skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 9, 12, 14, and 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Arrowsmith et. al.** (US 5,776,951).

The following analysis is based on factual inquiries set forth in *Graham et. al. v. John Deere Co.* (148 USPQ 459), and pertinent case laws in chemical art.

4. On column 1, Arrowsmith et. al. disclose a genus of formula I with the following structure:



Wherein:

X is $-\text{C}(\text{O})\text{NR}^2$ (with R^2 as hydrogen),...;

W is $-\text{RC}(\text{O})-$ (with R as hydroxy),..., which gives the equivalent of the oxamic acid side chain of the species recited in the instant claim 9;

Y is $-(\text{CH}_2)_n\text{-O-}(\text{CH}_2)_p$ (with "n" and "p" equal 0),...;

E is $-(\text{CH}_2)_r\text{-S}(\text{O})_t\text{-(CH}_2)_s$ (with "r" and "s" equal 0, while "t" equals 2),...;

Z is an aryl substituted with halo,...

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The disclosed genus can inhibit coenzyme A: cholesterol acyltransferase, which in turn can lower plasma cholesterol and lipoprotein just like the methods claimed herein. The disclosed genus differs from the claimed species by having the oxamic acid chain at the different position on the phenyl ring. However, compounds having substituents on different positions are positional isomers. Because positional isomers have similar substituents, they are expected to have the share the same physiological activity, and thus, are not deemed patentably distinct absent evidence of superior unexpected results as has been ruled in **In re Crounse**, 150 USPQ 554; **Ex parte Engelhardt**, 208 USPQ 343 regarding positional isomerism. Besides, positional isomers are by-products of each other. Thus, when one skilled in the art prepare one, the other is also expected. So at the time of the invention, it would have been obvious for one skilled in the art to make the species claimed herein as a cholesterol and lipoprotein lowering agent in view of the guidance provided by Arrowsmith et. al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

T. Truong

March 23, 2001

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